

Novartis PAC Press

Learning about the Novartis Political Action Committee

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The Uncertain Path of Follow-on Biologics

Some say, imitation is the most sincere form of flattery. That is until the subject of follow-on biologics is mentioned.

Biologics are medicines made in living systems, such as blood products for hemophilia, vaccines, and hormones, such as insulin and human growth hormone. Biosimilars — or follow-on biologics — are subsequent versions of off-patent biologics made by different sponsors. However, biologics are not usually as simple as the more common, small molecule drugs. The active ingredients are generally larger-molecules that include proteins and often sugars, and they can be complex mixtures that are often sensitive to manufacturing process changes.

What all the fuss is about

Opponents to follow-on biologics argue that they will be unsafe and that small variations in the composition may have serious health consequences for patients. However, a limited number of follow-on biologics, such as hormones, have been safely regulated as drugs under the Federal Food Drug & Cosmetics Act. The European Union is also using a specially developed biosimilar regulatory pathway and approval process that relies on “comparability” to an existing approved biologic product.

Most biologics in the US are regulated under the Public Health Service Act (PHS Act), and the FDA currently has no explicit statutory authority to license biosimilars of these products. FDA believes that new legislation is required to enable them to approve such biosimilars to be sold to US patients.

Last June, the Senate HELP (Health, Education, Labor and Pensions) committee passed the “Biologics Price Competition and Innovation Act” and is now waiting for the House to take action. Follow-on biologics may not be able to provide discounts as steep as traditional generics, but some of the biologic medications run hundreds of thousands of dollars and so the individual patient savings could be quite significant.

“Even a 20 to 40 percent savings adds up to a lot,” says David Drake, Executive Director of Federal Government Relations. “In addition to providing savings to patients and payors, competition also spurs innovation of new medications.”

Top priorities

According to David, there are three major issues that need to be addressed in any biologics legislation:

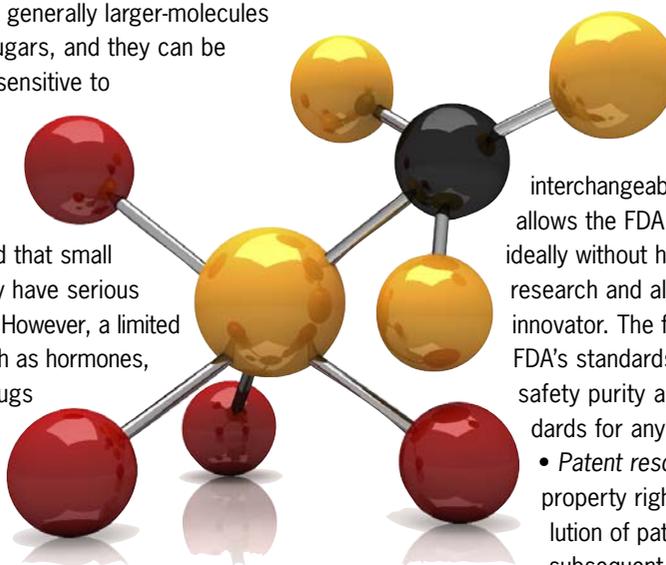
- *Scientifically-sound pathway* — provide a means for expedited approval (similar to that for generic drugs) of an

interchangeable biologic when the science allows the FDA to reach this decision, and ideally without having to duplicate all the research and all the clinical trials done by the innovator. The follow-on biologic must meet FDA’s standards of “highly similar” to ensure safety purity and potency (the current standards for any biologic).

- *Patent resolutions* — protect intellectual property rights while encouraging the resolution of patent disputes in advance of any subsequent sponsor’s readiness to launch.
- *Exclusivity* — establishing a fair period of market exclusivity for innovator biologics so the sponsor of the innovator biologic can earn an adequate financial return on the high investments made.

The House has introduced several bills, the most recent of which is the Eshoo/ Barton “Pathway for Biosimilars Act”. The authors are trying to reach a consensus by using suggestions in previous proposals, but progress has been slowed by the distractions of an election year. Ajaz S. Hussain, PhD, Vice President and Global Head of Biopharmaceutical Development at Sandoz testified in support of follow-on biologics to the Senate HELP committee in March 2007 and components of the Senate bill are incorporated in Eshoo/Barton.

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Political Views: Bob Franks, President, HealthCare Institute of New Jersey

Bob Franks is President of the HealthCare Institute of New Jersey (HINJ). Established in 1997, HINJ is an association of 25 research-based pharmaceutical and medical technology companies in New Jersey. He has been a leader in State politics and government for three decades and served four consecutive terms as Congressman for New Jersey's 7th district. PAC Press sat down with Mr. Franks recently to discuss the work of the Institute and the issues impacting the pharmaceutical industry.



“We can expect a great deal of legislation to come down the pike, specifically, access to quality health care.”

First of all, tell us a little about the HealthCare Institute of New Jersey.

New Jersey has long been called the ‘Medicine Chest of the World’ for good reason. Nearly half of the drugs sold around the world have a connection to New Jersey. In fact, New Jersey is home to more pharmaceutical companies than any other state in the country.

That said, the HealthCare Institute of New Jersey serves as a voice for the industry and works to build awareness of the industry’s impact on the quality of life and economics of the state.

As we go into this important election year, what are the top issues in the pharma industry that will likely come into play?

There are a few issues that will likely rise to the top. Patent law is a big one. Pharmaceutical companies spend billions of dollars to develop new drugs. They deserve to have their intellectual property protected vigorously.

Not surprising, price controls are another major issue. Again, with all the money spent bringing new products to the people who need them, it’s only fair that pharma companies be allowed to recoup their investment and make a profit. New Jersey pharmaceutical companies have been leaders in offering discounted, and even free, medicines to those in need. But stringent price controls are simply not the answer, and may even discourage innovation.

So, what role will you and HINJ play?

Regardless of which party wins the White House or controls Congress, the subject of health care will remain a top issue. We can expect a great deal of legislation to come down the pike, specifically, access to quality health care. Prescription medicines, of course, play a big part in this. It is our job to see that lawmakers have a balanced view of the issues so that they can make smart decisions. We exist to educate and inform leaders.

Toward this end, we regularly meet with policymakers on all levels, from the New Jersey Congressional delegation to the Governor and his staff to State leaders. Ultimately, we want to do our part to help protect these companies, which in turn are helping to save lives and improve the quality of life for many.

Can you point to some HINJ successes?

Well, there have been many, some small and some large. Let’s just take the issue of importation as an example of our incremental impact. Go back about five or six years and you’ll find that New Jersey’s Congressional delegation was lined up 9-4 against the industry position on the issue. Today, the tide has turned. The delegation now supports the industry position by that same ratio. We think we had something to do with that, as did PAC members.

That leads to our last question. What impact can Novartis PAC and its members have in the debate?

Our greatest asset is the people who work at companies such as Novartis, all of whom are doing their part in the drug development process, whether it’s in the lab or in the office. We need to make a connection between these people and key policymakers. That ‘connection’ often comes from PAC representation. A strong PAC, backed by eligible employee contributions, is quite powerful.

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“We’re hoping for some decisions this year, but the window of opportunity is getting smaller. Each presidential candidate has voiced support for the follow-on biologics, and the White House mentioned it in the President’s budget, but there was no dollar amount assigned,” adds David.

A leader in biosimilar development

Novartis is a global leader in the innovator biopharmaceutical industry with the approval and launch of 15 new products in the U.S. since 2000 — more than any other company. It also brought the first biosimilar (Ominitrope) and the first glycoprotein biosimilar (Binocrit) to the market in any highly regulated country. And Novartis has a large global network of modern biopharmaceutical companies facilities, including those in the US, Switzerland, France, Germany, Austria and Slovenia.

The development of biological products at Novartis spans the Pharma, Sandoz and Vaccines & Diagnostics divisions, which share teams and facilities. In fact, Novartis is unique among pharmaceutical companies in that it has large investments in both branded and generic medicines and believes that the same quality standards can, and should, be applied to both. Then patients can expect the same quality from all sponsors.

Although the current debate on follow-on biologics is emotionally charged at times, it is not dissimilar to the arguments that were made in 1984 when generics were introduced to the market. Yet, these medicines have proven safe and effective and facilitated much greater access for patients. They have also helped defend free-market pricing for all prescription medicines and so enabled the further investment in innovation. The future of medicine will eventually include follow-on biologics. The question is when.

And Now a Word from our Members...

In this recurring column, Novartis PAC members share their viewpoint on the issues of the day, as well as their reasons for supporting PAC efforts with both their hard-earned money and valuable time.

John Fitek, Sales Consultant

John Fitek believes that if you’re concerned about the future — from either a professional and/or a personal perspective — the time to get involved with Novartis PAC is now: “There’s a lot of legislation being proposed that directly impacts the pharmaceutical industry and our country’s healthcare. To make sure

change happens properly and not just for political reasons, you need to become a part of the process. Otherwise, you really don’t have a reason to whine if things don’t go well.”

So, why did John choose to become a PAC member? For one, drug importation is an important issue for him. In northern Michigan where he is a sales consultant, buses of senior citizens were regularly crossing the border to purchase less expensive medications. However, as John points out, it doesn’t matter if the country is one foot away or on the other side of the world. Other countries, even those similar to the US like

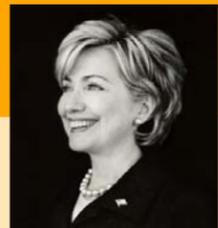
Canada, have different laws and drug safety requirements that offer no guarantee that an American is buying the same prescription medications approved in the US, even if they have a similar label.

John also keeps a watchful eye on state politics. He is very concerned by an effort by Blue Cross Blue Shield (BCBS) of Michigan to implement price controls. John believes this would effectively put smaller health insurance plans out of business. “If there’s going to be a price war, it should be aboveboard and visible to everyone. What BCBS is proposing would completely eliminate any competition from the process,” he notes. Novartis PAC is at the forefront of the price control issue — a key factor in why he lends support and makes his contribution.

At a recent District Planning Meeting, John spoke to his colleagues about supporting Novartis PAC. “More associates need to understand how political decisions directly affect them. I’m encouraging everybody I work with to get involved with Novartis PAC. Ultimately, we need many more members so we can have an even stronger voice when we work with Congress, state legislators and regulators.”

What Are Your Thoughts on PAC? If you’re a new member, or have been one for years, we want to hear your story, too.

Presidential Candidates: Where They Stand



	Hillary Clinton	Barack Obama	John McCain
Goal of Reform	Guarantee universal coverage or nearly universal coverage through a mix of private and expanded government insurance.	Guarantee universal coverage or nearly universal coverage through a mix of private and expanded government insurance.	Universal coverage is not a goal, as it would lead to a large government role in healthcare. Overall goal is to improve efficiency, reduce government spending, and reduce overall costs of healthcare
General Approach	Private and expanded public health insurance options where uninsured could access a new government-run plan option or other private plans.	Private and expanded public health insurance options where uninsured could access a new government-run plan option or other private plans.	Access to affordable, quality care by promoting efficiency and competition in the private market and encouraging private insurance options. Would remove favorable tax treatment of employer sponsored insurance and provide tax credits to all individuals who purchase health insurance.
Role of Government	Does not replace the current healthcare system with a single-payer, government-run plan. Builds on the current employment-based health insurance system and public programs (adding a new government-run option) and would impose greater regulation on insurers.	Does not replace the current healthcare system with a single-payer, government-run plan. Builds on the current employment-based health insurance system and public programs (adding a new government-run option) and would impose greater regulation on insurers.	Prefers a system in which people purchase insurance themselves in the individual marketplace (rather than in the workplace) with fewer requirements on insurers. Would change tax laws to do so.
Public Programs	Coverage through public programs such as Medicare and Medicaid continues; expansions of Medicaid and children's health insurance program for most vulnerable. New government-run plan option for uninsured.	Coverage through public programs such as Medicare and Medicaid continues; expansions of Medicaid and children's health insurance program for most vulnerable. New government-run plan option for uninsured.	Current coverage through public programs such as Medicare and Medicaid continues, but is not expanded.
Mandates to Obtain Coverage	Individuals required to have coverage; Employers must offer coverage or contribute to public plan option.	Children required to have coverage; Employers must offer coverage or contribute to public plan option.	No provision — opposes mandates on individuals and employers.
Premium Subsidies	Tax credits for working families.	Subsidies for lower income.	Tax credits for all who purchase coverage.
Cost Containment	Prevention initiative; investments in health information technology; disease management; promote insurer competition.	Prevention initiative; investments in health information technology; disease management; promote insurer competition.	Prevention initiative; investments in disease management; promote insurer competition; malpractice reforms.

This year's presidential election is undeniably one of the most exciting in recent history. It's filled with enough turnovers and come-from-behind moves to rival the last Super Bowl. Regardless of who is ultimately elected to the highest office, healthcare reform is at the forefront of the campaign.

"There are risks and potential opportunities for the pharmaceutical industry with all three Presidential candidates. Covering the uninsured is a higher priority for the Democratic candidates, while Senator McCain has focused on choice and efficiency in healthcare." says Bonnie Washington, Vice President of Health Policy.

While Novartis PAC does not get directly involved in the presidential race, we can provide a closer look at the positions each of the front-runners has taken regarding the issues that most impact Novartis and its associates:

Pharma-Related Provisions

	Hillary Clinton	Barack Obama	John McCain
Drug Prices	Would give federal government authority to negotiate drug prices in Medicare Part D; would allow importation.	Would give federal government authority to negotiate drug prices in Medicare Part D; would allow importation.	Risk of giving federal government authority to negotiate drug prices in Medicare Part D; has supported greater transparency of drug prices; would allow importation.
Generics	Would encourage faster introduction of generics.	Would encourage faster introduction of generics.	Would encourage faster introduction of generics.
	Supports establishment of new entity charged with conducting comparative effectiveness reviews of different therapies with goal to decrease costs.	Supports establishment of new entity charged with conducting comparative effectiveness reviews of different therapies with goal to decrease costs.	Has been silent on this issue.
Comparative Effectiveness Research/ Evidence-based medicine	Supports efforts to limit consumer advertising and increase oversight of drug companies' financial relationships with providers.	Has been silent on this issue, but would likely support efforts to limit consumer advertising and increase oversight of drug companies' financial relationships with providers.	Has been silent on these issues in campaign. However, because of bipartisan support, would likely support efforts to limit consumer advertising and increase oversight of drug companies' financial relationships with providers.
Direct-to-Consumer Advertising/ Sales and Marketing	Supports changes in patent laws to increase availability of generics.	Has been silent on this issue, but would likely support changes to increase availability of generics.	Has been silent on this issue.
Patents	\$110 billion a year in costs; financed from modernization and cost containment initiatives, cuts in payments to private Medicare plans, and discontinuing current tax cuts for upper income individuals.	\$60 billion a year in costs; financed from modernization and cost containment initiatives, cuts in payments to private Medicare plans, and discontinuing current tax cuts for upper income individuals.	Not yet specified.

Parting thoughts

Although there is strong public support for healthcare reform, passing ambitious programs through Congress can be a challenge. However with 47 million American uninsured and with premiums rising four times as fast as wages, it is inevitable that some form of change is near.



Congressional Departures Create Flux on “The Hill”

Washington political wags commonly refer to it as “The Casualty List,” or list of 25 Republicans and six Democrats in the House who have announced that they will not run for reelection, either because they are retiring or choosing to pursue other political positions. In addition, several incumbents lost their primary race and one recently passed away, creating yet more uncertainty about the ultimate composition of the 111th Congress in 2009. It is also still relatively early in the election year, and additional retirements could be announced in the coming weeks.

The last time there was such a disproportionate partisan breakdown of retirements was in 1958. For the Republicans to gain control of the House, they need a net gain of 17 seats which can only be accomplished by defeating a relatively large number of Democratic incumbents and successfully defending seats opened by Republicans — all of which is a long shot.

Senate turnover too

There is a unique situation brewing in the Senate as well. Democrats currently have a paper-thin, 51-vote majority. However, under Senate rules, 60 votes (a three-fifths majority) are needed to end filibusters to move legislation to vote. While picking up the additional 9 seats to obtain a three-fifths majority will be extremely difficult, a quirk in this election cycle gives Democrats a slight chance.

This year, 23 Republican Senators are up for re-election, including two interim Senators who were appointed to fill vacancies. In comparison, Democrats must defend only 12 seats. The challenge facing Republicans was compounded by the retirement of five incumbents. Many political pundits consider three of these seats to be very vulnerable to a Democratic takeover while only one of the Democratic positions to be at risk. The Senate races in three other states — New Hampshire, Colorado, and Minnesota — are generally considered to be toss-ups.

A look at the implications

Based on the foregoing analysis, what conclusions can be drawn about the 111th Congress at this early point in the election year?

First, Democrats are likely to increase their majority in the House enhancing their ability to pass legislation, shape policies, and pursue initiatives of importance to the party and, possibly, a Democratic President.

Second, it is probable that Democrats will pick up additional seats in the Senate and get close to a filibuster-proof, 60-vote majority. Obtaining the three-fifths majority might be difficult, but if Democrats get close to that point, it will be easier for them to persuade enough Republicans (especially moderates) on certain issues to move legislation.

Third, regardless of what happens in the actual elections, the large number of retirements will result in the loss of many policy-savvy, experienced legislators, particularly in the committees.

For example, the House Ways and Means Committee is generally considered to be the most powerful of all House committees because it has jurisdiction over taxes, health care and trade. There are 24 Republican members of this committee, but only nine will return assuming that they all win their elections. On the Democratic side of the Ways and Means Committee, the most senior five Members have over 130 years of Congressional experience, although only one is retiring.

With more than seven months left until the elections, the vagaries of the economy and the personal financial concerns of the electorate, the war in Iraq, and the pitched battle between Senators Clinton and Obama for the Democratic nomination, no result can be predicted with any element of certainty.

A look at the House Seats Opening Up

- **Tom Allen** (D-ME), 63, six terms (running for Senate)
- **Richard Baker** (R-LA), 59, 11 terms.
- **Barbara Cubin** (R-WY), 61, seven terms
- **Tom Davis** (R-VA), 59, seven terms
- **John Doolittle** (R-CA), nine terms (under investigation re: relationship to Abramoff)
- **Terry Everett** (R-AL), 71, eight terms
- **Mike Ferguson** (R-NJ), 37, four terms
- **Wayne T. Gilchrest** (R-MD), 62, nine terms
- **Dennis Hastert** (R-IL), 66, 11 terms
- **David Hobson** (R-OH), 71, nine terms
- **Kenny Hulshof** (R-MO), 49, six terms
- **Duncan Hunter** (R-CA), 59, 14 terms
- **Ray LaHood** (R-IL), 62, seven terms
- **Tom Lantos** (D-CA), 80, 14 terms (deceased 2/11/08)
- **Ron Lewis** (R-KY), 61, seven terms
- **Jim McCrery** (R-LA), 58, 11 terms
- **Michael McNulty** (D-NY), 60, 10 terms
- **Steve Pearce** (R-NM), 60, three terms
- **John Peterson** (R-PA), 69, six terms
- **Chip Pickering** (R-MS), 44, six terms
- **Deborah Pryce** (R-OH), 56, eight terms
- **Ralph Regula** (R-OH), 83, 18 terms
- **Tom Reynolds** (R-NY), 58, 5 terms
- **Jim Ramstad** (R-MN), 61, nine terms
- **Rick Renzi** (R-AZ), 49, three terms (recently indicted on 35 counts)
- **Jim Saxton** (R-NJ), 65, 12 terms
- **Tom Tancredo** (R-CO), 62, five terms
- **Mark Udall** (D-CO), 57, five terms (running for Senate)
- **Tom Udall** (D-NM), 59, five terms (running for Senate)
- **Jim Walsh** (R-NY), 60, 10 terms
- **Dave Weldon** (R-FL), 55 seven terms
- **Jerry Weller** (R-IL), 50, seven terms
- **Heather Wilson** (R-NM), 47, six terms (running for Senate)
- **Albert Wynn** (R-MD), 57, eight terms

Upcoming Senate vacancies

- **Wayne Allard** (R-CO), 65, 3 Senate terms and 3 House terms
- **Larry Craig** (R-ID), 63, 1 Senate term and 5 House terms
- **Chuck Hagel** (R-NE), 62, 2 terms
- **Pete Domenici** (R-NM), 76, 6 terms
- **John Warner** (R-VA), 81, 5 terms

Legislative Challenges Remain for 2008

While there may have been little progress on key healthcare issues since the end of 2007, they haven't been forgotten — quite the contrary.

Healthcare is a key platform on every politician's agenda and any of the issues below could be brought to the forefront before summer recess. And with Congressional campaigns under way, it's impossible to predict what will happen. One thing is certain, the pharmaceutical industry is particularly vulnerable in the following areas:

- **Importation** – Some lawmakers are advocating for the importation of drugs from foreign countries as a means of reducing patient costs. This would, however, expose Americans to medications that have not passed FDA scrutiny. A key point of contention.
- **Non-interference** – In Medicare Part D, the government is prohibited from negotiating price directly with manufacturers or pharmacists. There is a movement afoot to repeal this part of the act.
- **Sunshine Act** – All of the Pharma field force is required to report marketing activities such as the distribution of samples, “lunch and learns,” honorariums, etc. However, there is no uniformity in how this is done. Some lawmakers believe current practices aren't transparent enough. They have introduced legislation that would create a Health and Human Services website that discloses the details and recipients of these marketing efforts.

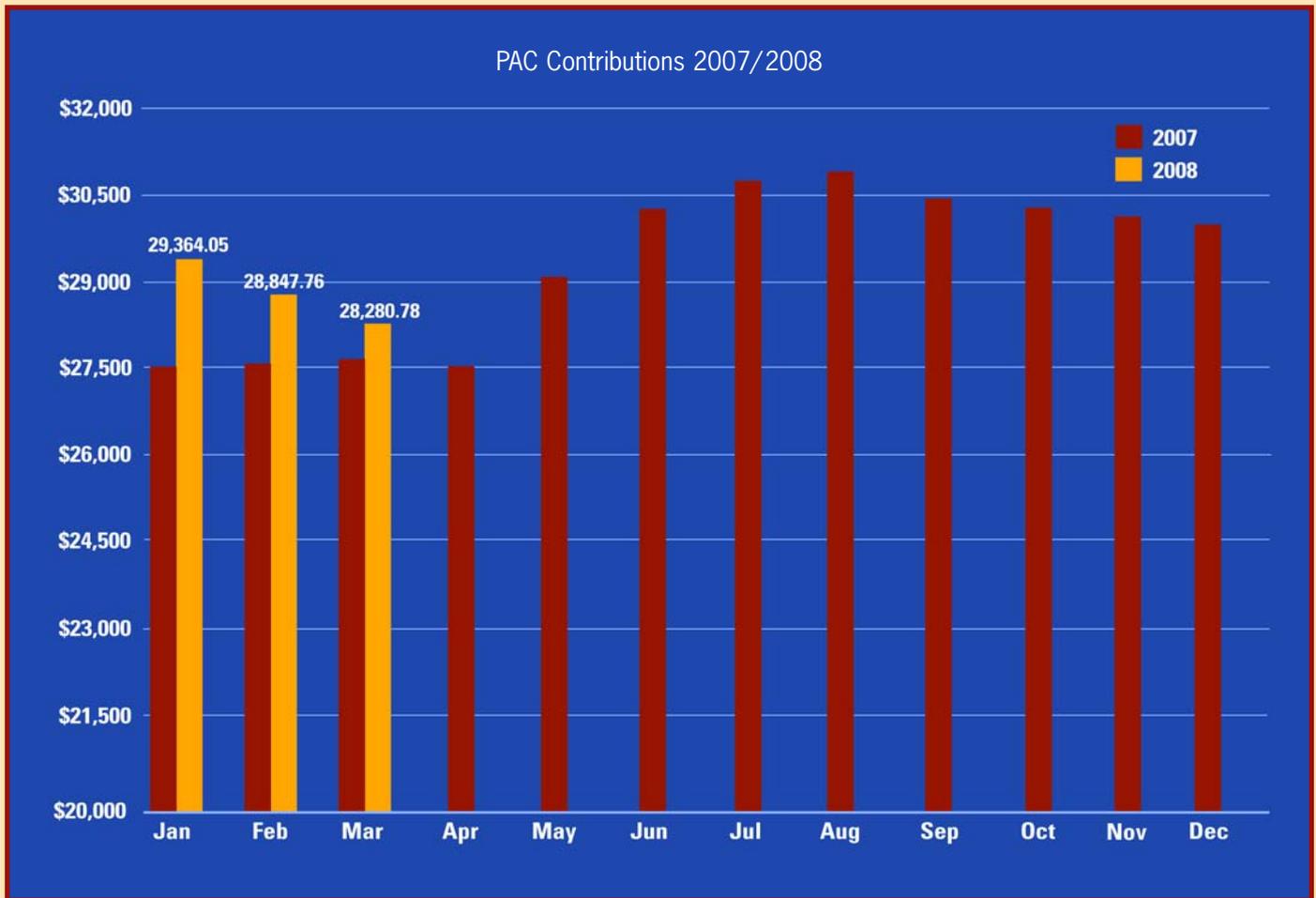
• **Medicaid rebates** – Medicaid rebates are currently 15.1 percent. There is movement to increase this amount to 20.1 percent to finance other healthcare-related legislation.

• **Patent reform** – Since passage in the House and Senate Judiciary Committee, opposition has risen over aspects of the Senate bill that could weaken patent protections for the innovator. Labor unions, the Pharma and biotech industries, universities, manufacturing and other organizations have expressed their concerns over the terms of the current bill.

• **Comparative effectiveness research** – Although this proposal was unsuccessful last December, it will most likely be reintroduced either as a standalone bill or as part of a larger Medicare package this summer. Research would look at health outcomes of new and existing drugs, medical devices and other treatments.

“It's difficult to reliably determine what will happen during an election year, especially in a politically charged environment like this,” says Dan Casserly, executive director federal government affairs. “Most likely, some action will be taken before the summer. After then, Capitol Hill will be preoccupied with the presidential elections and appropriation hearings, so not much else will get done.”

Novartis PAC... By the Numbers



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**Board terms expire at the end of the designated year*

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